North Dakota Department of Health
HIPAA Policy

Policy Title:	**Uses and Disclosures for Research Activities**	
Policy Number:	P-023	**Version**: 1.2 January 6, 2004
Reference:	45 CFR 164.512(i); 45 CFR 164.512(b)	
Applicability:	Department of Health	
Approved By:	Dr. Terry Dwelle, State Health Officer Arvy Smith, Deputy State Health Officer Darleen Bartz, HIPAA Coordinator, Privacy Officer	
Effective Date:	April 14, 2003 **Policy Repealed Effective January 31, 2004**	

Policy:

The NDDoH may use or disclose protected health information (PHI) for research as specified in the following procedure.

Exceptions:

None

Procedure:

- There are four ways NDDoH may use and disclose PHI for research purposes:
  - With the individual's specific written authorization. Such authorization must meet all the requirements described in the Authorization Policy;
  - If the information is de-identified or a limited data set as described in the Limited Data Set/Data Use Agreement and De-identified Health Information policies;
  - Without the individual's authorization if the NDDoH obtains documentation that an alteration to or waiver of the individual's authorization has been approved by either an Institutional Review Board (IRB) or the NDDoH privacy board.
    - If the approval was by an IRB outside of the NDDoH, the NDDoH privacy board must review for approval prior to the use or disclosure.
  - If the research is on decedent's information, a Data Use Agreement will be utilized releasing the minimum necessary information. No IRB or privacy review board review is needed.

- The NDDoH privacy board must:
  - Have NDDoH staff members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
  - Include at least one member who is not affiliated with the NDDoH or with any entity conducting or sponsoring the research and not related to any person who is affiliated with any such entities;

  - Not have any member participating in a review of any project in which the member has a conflict of interest.

- Prior to the research, the NDDoH must ensure:
  - The use or disclosure of PHI is necessary to prepare a research protocol or preparatory purpose;
  - No PHI is to be removed from the NDDoH by the researcher until approval is granted;
  - The PHI requested is necessary for the research purposes.

- For a use or disclosure permitted based on documentation of approval of an alteration or waiver, the documentation must include:
  - A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;
  - A statement that the IRB or privacy board has determined that the alteration or waiver of authorization satisfies the following criteria:
    - The use or disclosure of PHI:
      - Involves no more than a minimal risk to the privacy of individuals;
      - Includes an adequate plan to protect the identifiers from improper use and disclosure;
      - Includes an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or retention is required by law;
      - Includes an adequate written assurance that PHI will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI would be permitted;
      - Would not adversely affect individuals' rights.
    - Notification of the research results, when appropriate, to the individual.
    - The research could not be conducted without the waiver or alteration.
    - The research could not be conducted without access to and use of the PHI.
  - A brief description of the PHI for which use or access has been determined to be necessary by the IRB or privacy board;
  - A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures as follows:
    - The IRB must follow the Common Rule as defined in the Federal Register.
    - A privacy board must review the proposed research at meetings at which a majority of the privacy board members are present, including one member who is not affiliated with the NDDoH or with any entity conducting or sponsoring the research and not related to any person who is affiliated

with any of those entities. The alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting unless the privacy board elects to use an expedited review procedure;

- An expedited review procedure may be used if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought. The review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board or by one or more members of the privacy board as designated by the chair.

- The documentation of the alteration or waiver of authorization must be signed by the chair or other member as designated by the chair of the IRB or the privacy board.

- For release of PHI for research on decedent's information, the following steps will be taken:
  - All requests for release of information for research on decedent's information are to be sent to the NDDoH HIPAA Coordinator.
  - The NDDoH must obtain representation from the researcher that the use or disclosure sought is solely for research on the PHI of decedents, there will be no attempt to contact family members, the PHI requested is necessary for the research purposes, and documentation of the death of such individuals, (if applicable).
  - The requestor will be contacted to inquire which information is needed for the research. Only the minimum necessary information needed will be disclosed.
  - A proposed Data Use Agreement will be returned to the requestor for review. The requestor must sign and date the Agreement and return to the NDDoH HIPAA Coordinator.
  - The appropriate NDDoH Program Representative will be requested to review the Data Use Agreement, sign and date.
  - The NDDoH HIPAA Coordinator will review the completed Data Use Agreement, sign and date.
  - A Data Use Agreement number will be assigned to the Data Use Agreement when the Agreement has been finalized and all appropriate signatures have been obtained.
  - A copy of the signed Data Use Agreement will be given to the requestor and the appropriate NDDoH Division. A copy will also be maintained by the HIPAA Coordinator. The signed original will be forwarded by the HIPAA Coordinator to the NDDoH Administrative Services Section. The original will be maintained by the Administrative Services Section in a secure file.
  - Documentation of the information released (actual copies, database fields, etc.) is to be retained by the appropriate NDDoH Division.

- When the NDDoH is operating as a Public Health Authority, NDDoH is authorized to obtain and use individual information without authorization for the purpose of preventing or controlling disease, injury or disability and for the conduct of public health surveillance, investigation and intervention. In addition to these responsibilities, NDDoH may collect, use or disclose information without individual authorization to the extent that such collection, use or disclosure is required by law. When NDDoH uses information to conduct studies pursuant to such authority, no additional individual authorization is required nor does this policy require IRB or privacy board waiver of authorization. Other applicable laws and protocols continue to apply to such studies. Unless the public health authority status is known, the NDDoH will require a Business Associate Agreement or Data Use Agreement to be completed. Dependent upon reason for the request from a public health authority, the NDDoH may require a Business Associate Agreement or Data Use Agreement be completed prior to release of PHI to another public health authority.

Related Forms:

None

Definitions:

NDDoH – North Dakota Department of Health

Protected Health Information – Individually identifiable health information that is transmitted or maintained by electronic media or transmitted or maintained in any other form or medium

Individually Identifiable Health Information – Health information which includes demographic information that relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual and that identifies the individual or there is a reasonable basis to believe the information can be used to identify the individual

Electronic Media – Electronic storage media including memory devices in computers and any removable/transportable digital memory medium such as magnetic tape or skid, optical disk or digital memory card; or transmission media used to exchange information already in electronic storage media. Transmission media includes the internet, extranet, leased lines, dial-up lines, private networks and the physical movement of removable/transportable electronic storage media

Research – Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

Public Health Authority – An agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate